



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,319	09/18/2002	Mary K. Crow	5983/1G123-US2	1541
7590	09/29/2006		EXAMINER	
Darby & Darby 805 Third Avenue New York, NY 10022-7513			GAMBEL, PHILLIP	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/088,319	CROW ET AL.
	Examiner Phillip Gabel	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 7/5/06.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-9 is/are pending in the application.
 - 4a) Of the above claim(s) 4-9 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

Art Unit: 1644

Detailed Action

1. Applicant elect with traverse Group I (claims 1-3) in Response to Restriction Requirement, filed 7/5/06. The traversal is based upon the submission that the special technical feature over Webster et al. (Arthritis and Rheumatism 42: 1291-1296, 1999; Webster versus Li et al.) and Gomolka et al. (J. Mol. Med. 73: 19-29, 1995) is that the targeted gene region encoding for the CD40 ligand (CD40L) described by the prior art and that of the instant application are different.

The examiner appreciates applicant's noting the proper authorship of Webster (versus Li) and apologizes for any inconvenience to applicant in this matter.

For examination purposes, the recitation of "having" is the same as the recitation of "comprising".

It is noted that the claimed "nucleic acids" recite "having" which leaves the claim open for the inclusion of unspecified ingredients even in major amounts.

See MPEP 2111.03.

Given that the prior art teaches genomic nucleic acids encoding CD40L isolated from rheumatoid arthritis patients and that the claimed promoter region is an identifying characteristic of individuals at risk or suffering from the rheumatoid arthritis, as described in the instant application or published in WO01/02496,

The prior art nucleic acids anticipate or render obvious the claimed nucleic acids comprising a promoter region for CD40L from rheumatoid arthritis patients.

That the prior art focused on gene regions other than the promoter region does not detract from the prior art teachings of genomic nucleic acids for CD40L from rheumatoid arthritis patients.

Given that MacDonald et al. (J. Clin. Invest. 100: 2404-2414, 1997) focused on RNA and cDNA rather than genomic DNA, this reference does not stand as a prior art under 35 USC 102. However, given the obviousness of isolating and manipulating genomic as well as cDNA / RNA of a gene of interest, including the CD40L and its expression in normal as well as individuals with various immunoregulatory or autoimmune conditions, at the time the invention was made, one of ordinary skill in the art would have been motivated to isolate the genomic DNA of CD40L expressed in the rheumatoid arthritis patients taught by MacDonald et al. for various studies and assays associated with the expression of CD40L in these autoimmune patients at the time the invention was made.

Claims 1-3 are under consideration in the instant application.

Claims 4-9 have been withdrawn as being drawn to non-elected inventions.

2. Applicant's provision of the correspondence from Jane Diamond, the Managing Editor of Arthritis & Rheumatism (Exhibit 1, filed 7/5/06) stating that the mailing date was September 30, 1999 for Li et al. (Arthritis & Rheumatism 42(9) supplement, S1-S, September 1999), which was subsequent to applicant's priority date is acknowledged.

However, the priority date of the instant claims is ambiguous and may be deemed to be the filing date of the priority application PCT/ US00/24966, filed 9/13//2000, as the previous priority application USSN 60/153,625, filed 9/13/1999, may not support the claimed limitations of the instant application, encompassing

"an isolated and purified nucleic acid having the sequence of residues 331-455 of SEQ ID NO: 2" and "vectors" and "cells", broadly recited herein.

While the provisional priority document appears to disclose preliminary studies associated with a genomic sequence and alterations in a proximal CD40L promoter, The generic recitation of the current claims is not readily apparent.

Applicant should present a detailed analysis as to why the claimed subject matter has clear support in the earliest priority application USSN 60/153,625.

Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. 112, first paragraph.

Given the ambiguity of the priority date of the instant claims, certain prior art rejections are made under 35 USC 102(a)(b).

3. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ® or ™ symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP 608.01.

See page 35, line 17 of the instant specification.

Applicant is required to review the instant application for any additional hyperlinks.

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. This is a 35 U.S.C § 112, first paragraph, "written description" (and not new matter).

Claims 1-3 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

There is insufficient written description of the genus set forth in instant claim 1, which recites

"an isolated and purified nucleic acid having the sequence of residues 331-455 of SEQ ID NO: 2" and "vectors / cells" having / comprising said "nucleic acid".

These nucleic acids include continuous or discontinuous regions encoding CD40L in addition to the claimed promoter region of CD40L from rheumatoid arthritis, and may also contain additional coding and non-coding regions and, in turn, encompass the "gene". In addition, the invention could embrace any substitution, insertion or deletion change of nucleotides throughout the entire stretch of nucleotides found in the reference sequence and may or may not be specific for CD40L. Such nucleic acids could have any sequence at all attached to the defined "residues 331-455 of SEQ ID NO: 2". There is no limitation as to the nature of the rest of the molecule and no requirement that it have any particular function. The claims thus encompass nucleic acids that vary widely in structure and function. Reliance upon a promoter region alone is not sufficient to describe a genus that includes nucleic acids of such variable structure and function.

For example, a description of a genus of nucleic acids may be achieved by means of a recitation of a representative number of nucleic acids, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Such sequences do not meet the written description provision of 35 USC 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

In the instant claims, there is insufficient support for nucleic acids other than the defined "residues 331-455 of SEQ ID NO: 2" and there are no common structural features or common function specified or recited in the claims by which one of skill could identify other members of the claimed genus. Thus the skilled artisan would not conclude that Applicant was in possession of the genus of nucleic acids having / comprising "residues 331-455 of SEQ ID NO: 2" or the promoter region of CD40L from rheumatoid arthritis patients alone.

The skilled artisan cannot envision all the contemplated nucleotide sequences by the detailed chemical structure of the claimed polynucleotides and therefore conception can not be achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483.

Applicant has not disclosed any information which is 3' and 5' to "residues 331-455 of SEQ ID NO: 2" or the promoter region of CD40L from rheumatoid arthritis patients alone and 4 and therefore clearly lacks written description for the broad class of nucleic acids comprising "residues 331-455 of SEQ ID NO: 2".

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

The instant claims do not provide sufficient structural and functional characteristics coupled with a known or disclosed correlation between function and structure. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genera of "B7-2 fusion protein encoding nucleic acids" encompassing "first peptide / second peptide encoding nucleic acids".

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement makes clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3).

Art Unit: 1644

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

"Adequate written description requires a precise definition, such as by structure, formula, chemical name or physical properties, not a mere wish or plan for obtaining the claimed chemical invention." Id. at 1566, 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). Also see Enzo-Biochem v. Gen-Probe 01-1230 (CAFC 2002).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicant is invited to limit the invention to the disclosed human and mouse B7-2 encoding nucleic acids as the first peptide encoding nucleic acids and rely up the known immunoglobulin constant region encoding nucleic acids as the second peptide encoding nucleic acids to obviate this rejection.

While immunoglobulin constant regions, including their use in fusion proteins were a known class of molecules, including the nucleic acids encoding said immunoglobulin constant regions at the time the invention was made, the instant specification provides insufficient information concerning nucleic acids that encode a second peptide that provides possession of a second nucleic acid that corresponds to a moiety that alters the solubility, binding affinity or valency of the first peptide."

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3 are rejected under 35 U.S.C. § 102(a) as being anticipated by for Li et al. (Arthritis & Rheumatism 42(9) supplement, S1-S, September 1999) (892; of record) (see Abstract).

As pointed out above, given the uncertainty of the priority of the instant claims, this rejection is made under 35 U.S.C. § 102(a).

Art Unit: 1644

Lin et al. teach an altered nucleotide sequence in the promoter region of CD40, including the substitution of a cytosine for an adenine at position -135. Given the isolation, screening, characterization, comparisons and assays indicated in the Abstract by the co-inventors, the ordinary artisan would have immediately envisaged that the promoter region was stored and manipulated with vectors and host cells, as routine in the recombinant methodology at the time the invention was made by the ordinary artisan.

Also, given the description of the nucleic acid substitution and the known CD40L at the time the invention was made, the claimed sequence of the known CD40L promoter with the cytosine substitution was taught in the prior art.

Further, it is noted that given the presentation of the Abstract at the Conference/Meeting and the manner in which reference / information appears to have been presented, copying of information that was presented would have been relatively simple undertaking for those to whom it was presented / displayed.

See In re Klopfenstein, 72 USPQ2d 1117 (CA FC 2004).

If applicant does satisfy priority for the instant claims back to the provisional USSN 60/153,625,

then this rejection will be withdrawn in view of the correspondence from Jane Diamond, the Managing Editor of Arthritis & Rheumatism (Exhibit 1, filed 7/5/06) stating that the mailing date was September 30, 1999 for Li et al. (Arthritis & Rheumatism 42(9) supplement, S1-S, September 1999), which was subsequent to applicant's priority date.

8. Claims 1-3 are rejected under 35 U.S.C. § 102(a)(b) as being anticipated by Webster et al. (Arthritis & Rheumatism 42: 291-1296,1999) (892, of record) (see entire document) and as further evidenced by Crow et al. (WO 01/019844) (see entire document).

As pointed out above, given the uncertainty of the priority of the instant claims, this rejection is made under both 35 U.S.C. § 102(a)(b).

Webster et al. teach the isolation of the gene for CD154 (i.e. CD40L) in a male patient with an aggressive form of polyarticular arthritis. Given the isolation and the analysis of the gene for CD154, the ordinary artisan would have immediately envisioned that the prior art isolated the promoter region of the gene for CD154 and the use of vectors and host cells to manipulate said gene at the time the invention was made.

Comparison of the instant products with prior art is difficult since the Office is not equipped to manufacture the claimed product and/or prior art products that appear to be related and conduct comparisons

Art Unit: 1644

The disclosure of Crow et al. (which is the published PCT of the instant application USSN 10/088,319) describes the expression of the claimed promoter sequence in patients, particularly male patients, with arthritis.

Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced gene for CD154 in a patient with arthritis.

Also, it is noted that the claimed methods recite "having" which is interpreted the same as "comprising" which leaves the claim open for the inclusion of unspecified ingredients even in major amounts. See MPEP 2111.03

In addition, Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999) stands for the position that "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

9. Claims 1-3 are rejected under 35 U.S.C. § 102(b) as being anticipated by Gomolka et al. (J. Mol. Med. 73: 19-29, 1995) (892; of record) (see entire document) and as further evidenced by Crow et al. (WO 01/019844) (see entire document).

Gomolka et al. teach the identification and isolation of various genes associated with increase risk to develop rheumatoid arthritis, including the gene for CD40L, from 183 patients with rheumatoid arthritis (see entire document, including Materials and Methods). Given the isolation and the analysis of the gene for CD40L from a large number of patients with rheumatoid arthritis, the ordinary artisan would have immediately envisioned that the prior art isolated the promoter region of the gene for CD40L and the use of vectors and host cells to manipulate said gene at the time the invention was made.

Comparison of the instant products with prior art is difficult since the Office is not equipped to manufacture the claimed product and/or prior art products that appear to be related and conduct comparisons

The disclosure of Crow et al. (which is the published PCT of the instant application USSN 10/088,319) describes the expression of the claimed promoter sequence in patients, particularly male patients, with arthritis.

Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced gene for CD154 in a patient with arthritis.

Also, it is noted that the claimed methods recite "having" which is interpreted the same as "comprising" which leaves the claim open for the inclusion of unspecified ingredients even in major amounts. See MPEP 2111.03

In addition, Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999) stands for the position that "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

10. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gomolka et al. (J. Mol. Med. 73: 19-29, 1995) (892, of record) AND/OR Webster et al. (Arthritis & Rheumatism 42: 291-1296, 1999) (892; of record) AND/OR MacDonald et al. (J. Clin. Invest. 100: 2404-2414, 1997) (892; of record) in view of the art known practices to isolate and manipulate genomic sequences, including the regulatory regions such as the promoter region, as acknowledged on pages of the instant specification and taught by Schubert et al. (J. Biol. Chem. 270: 29623-26927, 1995) (1449) and Seyama et al (Hum Genet 97: 190-185, 1996) and as further evidenced by Crow et al. (WO 01/019844) (see entire document).

The teachings of Gomolka et al. and Webster et al. are set forth above.

Consistent with these above-mentioned teachings, MacDonald et al. teach the isolation and expression of CD40L in 21 patients with rheumatoid arthritis (see Methods and Results) and the importance of its expression in this disease as well as in other autoimmune diseases and its implications in therapy (see entire document, including Discussion).

Gomolka et al., Webster et al. and MacDonald et al. differ from the claimed products by not describing the particular promoter sequence in the isolation of nucleic acids encoding CD40L in patients with rheumatoid arthritis.

Given the obviousness of isolating and manipulating genomic as well as cDNA / RNA of a gene of interest, (e.g. see Detailed Description of the Invention, including page 14, lines 11-15; page 23, paragraph 2), including the CD40L and its expression in normal as well as individuals with various immunoregulatory or autoimmune conditions, at the time the invention was made, as taught by Schubert et al. (see entire document) and Seyama et al. (see entire document),

one of ordinary skill in the art would have been motivated to isolate the genomic DNA of CD40L expressed in the rheumatoid arthritis patients taught by Gomolka et al., Webster et al. and MacDonald et al. for various studies and assays associated with the expression of CD40L in these autoimmune patients at the time the invention was made. Given the importance and interest in the expression of CD40L in different autoimmune diseases and in particular rheumatoid arthritis as well as the structural analysis associated with expression and function of CD40L in these patients, the ordinary artisan would have been motivated to isolate and express the nucleic acids encoding the promoter region of the CD40L in patients with rheumatoid arthritis to determine the expression and regulations as well as differences in comparison to normal patients as well as other patients with other immunologically related diseases or conditions at the time the invention was made. Further, it was conventional to manipulate and express nucleic acids of interest via the use of vectors and host cells comprising said nucleic acids of interest at the time the invention was made.

In further evidence that genomic nucleic acids encoding CD40L from patients with rheumatoid arthritis would have the claimed promoter sequence,

the disclosure of Crow et al. (which is the published PCT of the instant application USSN 10/088,319) describes the expression of the claimed promoter sequence in patients, particularly male patients, with arthritis.

Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced gene for CD154 in a patient with arthritis.

Also, it is noted that the claimed methods recite "having" which is interpreted the same as "comprising" which leaves the claim open for the inclusion of unspecified ingredients even in major amounts. See MPEP 2111.03

Art Unit: 1644

In addition, Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999) stands for the position that "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gabel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phillip Gabel, Ph.D., J.D.

Primary Examiner

Technology Center 1600

September 25, 2006

